K073427

Dornier MedTech America, Inc.

AUG 20 2008

Medilas D Family Lasers

510(k) PREMARKET NOTIFICATION

SECTION 6

510(K) Summary of Safety and Effectiveness

Intended Use:	The Dornier Medilas D Family Lasers, specifically the *Medilas D Litebeam, Medilas D LiteBeam +, Medilas D UroBeam, Medilas D MultiBeam, Medilas D FlexiPulse and Medilas D MagnaPulse*, are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, and Radiology. The Dornier Medilas D Family Lasers, specifically the *Medilas D Litebeam, Medilas D LiteBeam +, Medilas D UroBeam, Medilas D MultiBeam, Medilas D FlexiPulse and Medilas D MagnaPulse*, are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux. The Dornier Medilas D Family Lasers, specifically the *Medilas D UroBeam, Medilas D MultiBeam, Medilas D FlexiPulse and Medilas D MagnaPulse*, are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85 cc.
Technological Characteristics:	From a clinical perspective and comparing design specifications, the Dornier *Medilas D Family Lasers* and the predicate devices are substantially equivalent. Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that no significant differences exist between the proposed diode lasers and the predicate devices. Dornier MedTech America, Inc. believes the minor differences of the *Medilas D Family Lasers* ant its predicates lasers should not raise any concerns regarding the overall safety or effectiveness.
Performance Data:	While no performance standards have been established for Diode lasers under Section 514 of the Federal Food, Drug,

and Cosmetic Act, the Dornier Medilas D Family Lasers are in compliance with class IV performance standards for light emitting products promulgated under the Radiation Control for Health and Safety Act of 1968. See 21 C.F.R. §1040.10 and §1040.11. The lasers also comply with the applicable requirements of the following voluntary standards: IEC 60601-1, IEC 60601-1-6, IEC 60601-2-22, IEC 60825-1, and European Medical Device Directive (CE).

nclusion:

Based on the technological characteristics and overall performance of the devices, Dornier MedTech America, Inc. believes that the *Medilas D Family Lasers* and the predicate devices selected are substantially equivalent and that the differences between the devices are minor which do not raise new issues of safety or effectiveness.

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Dornier MedTech America, Inc. 1155 Roberts Blvd. Kennesaw, GA 30144
Contact Person:	Theron Gober Quality and Regulatory Manager
Phone Number:	770-514-6204
Fax Number:	770-514-6288
Establishment Registration Number:	1037955
Date Prepared:	October 1, 2007
Device Trade Name(s):	Medilas D Family Lasers, including: ▪ *Medilas D Litebeam* ▪ *Medilas D Litebeam +* ▪ *Medilas D Urobeam* ▪ *Medilas D Multibeam* ▪ *Medilas D FlexiPulse* ▪ *Medilas D MagnaPulse*
Device Common Name:	Diode Laser System
Classification Name:	GEX – Laser Instrument, Surgical Powered
Predicate Device(s):	*Medilas D Compact* (K982629, K003993) *Medilas D fibertom* (K982629, K003993) *Medilas D SkinPulse* (K000072, K020339) *Medilas D SkinPulse* S / D940 (K003993, K020339)
General Device Description:	The Dornier *Medilas D Family Lasers* are continuous-wave diode laser emitting laser radiation in the invisible range of 940 nm. Each is calibrated during the manufacturing process and during service calls. The end-user does not calibrate fibers for this system. The *Medilas D Family Lasers* incorporate a graphic display panel, which shows laser operating parameters, application modes, time functions, system status and messages for the user. The *Medilas D Family Lasers* feature several operating modes, including Standard, Fibertom, LITT and LPS. The lasers can be used in contact or non-contact open surgery with or without handpieces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 2008

Dornier Medtech America, Inc.
% Theron Gober
Quality and Regulatory Manager
1155 Roberts Boulevard
Kennesaw, Georgia 30144

Re: K073427
Trade/Device Name: Medilas D Family Lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulatory Class: II
Product Code: GEX
Dated: August 14, 2008
Received: August 15, 2008

Dear Theron Gober:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Medilas D Family Lasers

Indications for Use

The Dornier Medilas D Family Lasers, specifically the *Medilas D Litebeam, Medilas D LiteBeam +, Medilas D UroBeam, Medilas D MultiBeam, Medilas D FlexiPulse and Medilas D MagnaPulse*, are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, and Radiology.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k093927